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TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED
PATENT AND TRADEMARK OFFICE EMPLOYEE.**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 040849/0187

In re patent application of

Yu WANG *et al.*

Serial No. 10/063,357 Group Art Unit: 2882

Filed: April 15, 2002 Examiner: Unknown

For: TOMOSYNTHESIS X-RAY MAMMOGRAM SYSTEM AND METHOD WITH AUTOMATIC DRIVE SYSTEM

ATTENTION GROUP ART UNIT 2882

TRANSMITTAL LETTER FOR PROPRIETARY INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56, 37 C.F.R. § 1.97, and M.P.E.P. § 724.02

Commissioner for Patents
Washington, D.C. 20231

Sir:

Attached hereto is a Proprietary Information Disclosure Statement submitting proprietary information to the Patent and Trademark Office in accordance with the requirements of 37 C.F.R. §1.56, 37 C.F.R. § 1.97, and M.P.E.P. § 724.02. Applicants respectfully request that the information be considered only by the Examiner in charge of the above-captioned application or other authorized Patent and Trademark Office employee.

This Proprietary Information Disclosure Statement is being filed under the provisions of 37 C.F.R. § 1.97(b) before the mailing of a first Action on the merits. No fee is due. However, in the event that the Patent Office determines that a fee is due for the

filing of this document, the Commissioner is hereby authorized to charge any such fee to Deposit Account No. 19-0741.

Respectfully submitted,

July 15, 2002

July 15, 2002

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ATTENTION: GROUP ART UNIT 2882

PROPRIETARY INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56 AND M.P.E.P. §§ 724 AND 724.02

Commissioner for Patents
Washington, D.C. 20231

Sir:

The following information disclosure contains proprietary information related to the machine illustrated in Figs. 6-13 in U.S. Patent Application No. 10/063,357.

Background

The present application is assigned to The General Electric Company ("GE"). To the best of the undersigned's understanding, more than one year prior to the filing of the present application, the machine illustrated in Figs. 6-13 of the present application was given by GE to Massachusetts General Hospital (the "Hospital") for experimental use

pursuant to a Research Agreement and a Confidentiality and Non-Use Agreement between GE and the Hospital. The Research Agreement, which was signed in 1996, is provided as Exhibit A. The Confidentiality and Non-Use Agreement, also signed in 1996, is included as Appendix B of the Research Agreement. Another Confidentiality and Non-Use Agreement between the parties, which was signed in 1995, is provided as Exhibit B.

The purpose of the experimental use was to establish operational parameters for the machine and to test the machine—a medical imaging device—on human research subjects. *See* Exhibit A, Research Agreement, para. 1.1. To support the costs of this clinical evaluation, a Memorandum of Agreement was signed in 1999 awarding a U.S. Army Medical Research Acquisition Activity Grant to the Hospital with GE acting as a subcontractor. The Memorandum of Agreement is provided as Exhibit C. The aforementioned experimental use involved only the machine of Figs. 6-13. To the best knowledge of the undersigned, the machine illustrated in Figs. 1-5 was not given to the Hospital and has not been publicly disclosed.

Experimental Use

Applicants submit that the testing of the machine illustrated in Figs. 6-13 at the Hospital is an "experimental use" under M.P.E.P. § 2133.03(e). A use or sale is experimental if it represents a *bona fide* effort to perfect the invention or to ascertain whether it will answer its intended purpose. *See* M.P.E.P. § 2133.03(e). As detailed in the Research Agreement, the purpose of the testing was to optimize the system, establish parameters for human imaging, and clinically evaluate the machine on human biopsy candidates. *See* Exhibit A, Research Agreement, App. A, para. 1-2. Further, four additional factors suggest an experimental purpose: (1) the nature of the machine is such that any testing has to be to some extent public, *see* M.P.E.P. § 2133.03(e)(4)(A); (2) the experimental testing was conducted for a substantial period of time, *see* M.P.E.P. § 2133.03(e)(4)(B); (3) the experimental testing was conducted under the supervision and control of GE, *see* M.P.E.P. § 2133.03(e)(4)(C); and (4) GE regularly inspected the invention during the period of experimentation, *see* M.P.E.P. § 2133.03(e)(4)(D).

It is indicative of an experimental purpose if the nature of an invention is such that any testing has to be to some extent public. *See* M.P.E.P. § 2133.03(e)(4)(A). As a medical device, the nature of the machine of Figs. 6-13 is such that clinical testing must be somewhat public because the device has to be evaluated on human biopsy candidates. *See* Exhibit A, Research Agreement, App. A, para. 2. Because GE's laboratory is not equipped and authorized for medical evaluations of human patients, a hospital or other medical facility was needed to conduct the testing.

It is further indicative of an experimental purpose if the testing has to be for a substantial period of time. *See* M.P.E.P. § 2133.03(e)(4)(B). As detailed in the Research Agreement, the study occurs over a substantial period of time and requires evaluation of a significant number of research subjects. The first part of the study, which involves optimizing the machine and determining the parameters for human imaging, was scheduled to commence in April 1996 and to be completed in August 1996. *See* Exhibit A, Research Agreement, App. A, para. 1, Schedule of Results Reporting. The second part of the study requires clinical testing of approximately 200 biopsy candidates. *See* Exhibit A, Research Agreement, App. A, para. 2.

Finally, it is indicative of an experimental purpose if the testing was conducted under the control and supervision of the inventor and the inventor regularly inspected the invention during the period of experimentation. *See* M.P.E.P. § 2133.03(e)(4)(C)-(D). GE maintained control of the machine by imposing reporting requirements on the Hospital, conducting regular on site inspections, and employing confidentiality restrictions. The reporting requirements specify (1) that GE and the Hospital conduct weekly conference calls, (2) that the Hospital issue biweekly reports of interim findings, (3) and that the Hospital submit monthly written evaluations of phantom, breast tissue, and human subject test results. *See* Exhibit A, Research Agreement, App. A, Schedule of Results Reporting. Further, GE was required to visit the Hospital each month to inspect the testing facility for a period of at least three hours. *See* Exhibit A, Research Agreement, App. A, Schedule of Results Reporting. Finally, the Confidentiality and Non-Use Agreements impose restrictions on GE and the Hospital concerning the use of confidential information obtained

during the course of the study. *See* Exhibit A, Research Agreement, App. B, para. 3-4; Exhibit B, Confidentiality and Non-Use Agreement, para. 3-4.

No Public Use

Applicants submit that the testing of the machine illustrated in Figs. 6-13 at the Hospital is not a "public use" under M.P.E.P. § 2133.03(a). "Public use" occurs when the inventor allows another person to use the invention without limitation, restriction, or obligation of secrecy. *See* M.P.E.P. § 2133.03(a)(3)(B). The testing of the machine at the Hospital was not a public use because GE and the Hospital executed two Confidentiality and Non-Disclosure Agreements that restricted the use of confidential information and imposed an obligation of secrecy on both parties. *See* Exhibit A, Research Agreement, App. B, para. 3-4; Exhibit B, Confidentiality and Non-Use Agreement, para. 3-4. Further, during testing on human patients, which involves placing the breast of a patient on the detector, the machine parts are completely hidden from the patient's view, as shown in Exhibit D. Specifically, the track and moving arms are completely hidden from the view of the patient by a shield. For comparison, an unshielded view of the machine is shown in Exhibit E. Even if the research subject were to look directly into the opening behind the detector, only the radiation source would be visible, but not the track and moving arms.

No Sale or Offer for Sale

Applicants submit that the machine illustrated in Figs. 6-13 was not "on sale" under M.P.E.P. § 2133.03(b). In determining if a sale or an offer to sell has occurred, the key question to ask is whether, under the totality of the circumstances, the inventor placed his invention on sale. *See* M.P.E.P. § 2133.03(III)(C). To the best knowledge of the undersigned, GE did not sell or offer to sell the machine of Figs. 6-13 to the Hospital.

Conclusion

Based on the foregoing disclosure, Applicants submit that the use of the machine illustrated in Figs. 6-13 at Massachusetts General Hospital meets the criteria for an

"experimental use" under M.P.E.P. § 2133.03(e), that the use was not a "public use," and that the machine was not "on sale" under 35 U.S.C. § 102(b).

Applicants consider the aforementioned disclosure to constitute proprietary information. Accompanying this Proprietary Information Disclosure Statement is a transmittal letter indicating that the materials contained herein are proprietary, as required by M.P.E.P. § 724.02. Applicants respectfully request that the Examiner consider the foregoing information and provide in the next official communication the information set forth in M.P.E.P. § 724.04(a).

Respectfully submitted,

July 15, 2002
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